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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/091,849 | 03/06/2002 | Steven T. Boyce | CUT / 02 | 8604 |

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EXAMINER

KOKABI, AZADEH

ART UNIT PAPER NUMBER

3743

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,849

Applicant(s)

BOYCE, STEVEN T.

Examiner

Azy Kokabi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 6-32 and 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5,33 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/28/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and Species B in Paper No. 7 is acknowledged. The traversal is on the ground(s) that claims 40-42 were erroneously listed with Group II method claims. This is found persuasive and claims 40-42 will be examined.

In Paper No. 7, Applicant requested that election include claims 1-5, 11, 18-26, 33-34, and 40-42. However, claims 11, 18-26 and 34 are drawn to Species A, an apparatus to prepare a biocompatible matrix that circulates coolant on at least two surfaces. Furthermore, unlike the elected Species B, Species A has three frames: a top frame, a bottom frame, and a center frame. Accordingly, claims 11, 18-26 and 34 have also been withdrawn from consideration.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-5, 40-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,711,172. Although the conflicting claims are not identical, they are not patentably distinct from each other. The Boyce patent claims ('172) discloses an apparatus having a multiple frames, a resilient gasket and a freezing chamber to form a dermal membrane. Likewise, the '849 Boyce application claims an apparatus having multiple frames, a gasket spacer, and a chamber to prepare a biocompatible matrix.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce (U.S. Patent No. 5,976,878).

Boyce discloses an apparatus for preparing composite skin replacement having a chamber (#29) to contain matrix-forming fluid (see at least column 8, lines 40-48). The chamber of Boyce is defined by at least a top planar surface (#22) and a bottom planar surface (#13) of a

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heat conductive material such as aluminum or steel (see at least column 7, lines 37-60).

Furthermore, the Boyce device comprises at least one gasket (#20) having a uniform thickness positioned between the top and bottom surface to define a perimeter of the chamber and capable of containing the matrix-forming fluid within the perimeter (see at least figure 8 and columns 7 and 8). Boyce further discloses a plurality of fasteners (#16) to fasten the apparatus and an open container to contain a coolant fluid (see top frame in figure 8 and column 8, lines 49-68). The chamber of the Boyce device is a bladder (#29).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce in view of Kushner et al (U.S. Patent No. 4,954,236).

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As previously, discussed in paragraph 5 above, Boyce discloses all the limitations as set forth. Boyce discloses a chamber with six surfaces, but fails to disclose a surface that is separately attachable to the box member.

Kushner discloses an apparatus for casting having five surfaces (#33, 43, 40, 44 and bottom of #10) and a separate sixth surface (#32) that attachable to the open chamber (#10). The removable enclosure permits contact with the underlying mold (see at least column 3, lines 20-28).

In view of Kushner, it would have been obvious to have provided a sixth surface that is removable to the mold in order to permit an opening to contact the underlying mold for purposes such as feeding material into the mold.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional references cited disclose various features, which are similar to those disclosed by Applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 6:30am to 4:00pm.

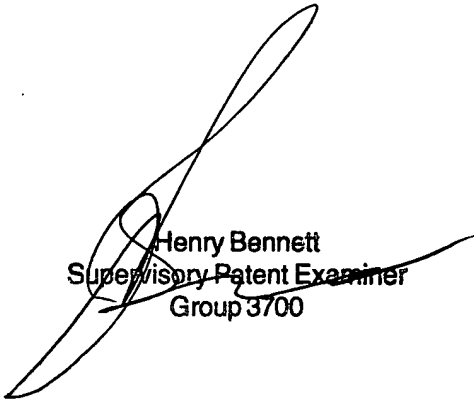
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AK

A handwritten signature, possibly reading "AK", with a stylized flourish.A large, stylized handwritten signature, possibly reading "Henry Bennett", written over the typed name and title.

Henry Bennett
Supervisory Patent Examiner
Group 3700